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Charles S. Schasteen

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EXAMINER

FORD, VANESSA L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/799,083	Applicant(s) SCHASTEEN ET AL.	
	Examiner VANESSA L. FORD	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/27/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-102 is/are pending in the application.
- 4a) Of the above claim(s) 1,7,14-16,19-22 and 27-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6,8-13,23-26 and 102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment filed December 29, 2008 has been entered. Claim 1, 7, 14-16, 19-22, and 27-101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on January 16, 2007.

Claims 2-6, 8-13, 23-26 and 102 are under examination.

Objection Withdrawn

2. In view Applicant's amendments and response the objection to the specification, pages 3-4, paragraph 3 is withdrawn.

Rejections Maintained

3. The rejection of claims 2-6, 8-10 and 23-26 under 35 U.S.C. 103(a), is maintained for the reasons set forth on pages 4-10 paragraph 4 of the Final Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 8-10 and 23-26 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al (*WO 00/50072 published August 31, 2000*) in view of Singh et al (*Cereal Chemistry, 72(4):344-348, 1995*).

Claims are drawn to a method of separating or isolating oocysts from a liquid suspension by the use of a hydrocyclone.

Conkle et al teach methods of isolating and separating oocysts from *Eimeria* species (oocysts known to cause coccidiosis) (see the Abstract). Conkle et al teach that encysted protozoa (oocysts) are obtained from feces, the suspensions or slurries can include significant amounts of undesirable suspended solids (pages 4-5). Conkle et al teach that the encysted protozoa require centrifugation and concentration of the protozoa (page 6). Conkle et al teach that the suspensions can include from about 1 up to about 20 weight percent solid or feces (page 5). Conkle et al teach that the separation methods of the invention include dense salt solutions including water and sodium chloride (page 5). Conkle et al teach that encysted protozoa need to be separated from suspension to achieved at least 70% encysted protozoa recovery (page 5). Conkle et al teach that encysted protozoa can be recovered or separated by salt flotation or gas flotation (page 5). Conkle et al teach that using salt flotation results in about 80 to 95 percent recovery (page 5). Conkle et al teach that the use of gas flotation results in about 20 to 90 percent recovery of encysted protozoa (page 7). However, Conkle et al teach that that gas flotation process rejects about 20 to 90 percent of encysted protozoa (page 7). Conkle et al teach that a need exists for a more efficient vaccination method (page 2). Conkle et al teach that this need would use other techniques to eliminate hazardous chemical such as potassium dichromate in processing the protozoa included in compositions used to vaccinate animals (page 2). Conkle et al teach that the methods of the invention are used to produce vaccines against avian coccidiosis (see the Abstract). Thus, Conkle et al teach the claim limitation that the host animals are from the class Aves.

Conkle et al do not teach hydrocyclones.

Singh et al teach a method of using hydrocyclones in separation processes (see the Abstract). Singh et al teach disclosed the use of the Doxie Type A single hydrocyclone (see the Abstract). Singh et al teach using hydrocyclones in separation processes increased the yield of product (see the Abstract). Singh et al also teach that using hydrocyclones reduced the amount of time of the separation process (see the Abstract). Singh et al teach that hydrocyclones eliminated the requirement of a large floor area, reduced the potential for error and more closely simulated the separation

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processes used in industrial operations (see the Abstract). Claim limitations such as density and appearance of the oocysts would be necessarily taught by the prior art references since oocysts are encysted from *Eimeria*. Claim limitations such as specific density ranges would be a matter of optimizing experimental parameters.

It would be *prima facie* obvious at the time the invention was made to modify the separation and isolation procedures as taught by Conkle et al to use hydrocyclones because Singh et al teach using hydrocyclones in separation processes increased the yield of product, reduced the amount of time of the separation process and eliminated the requirement of a large floor area. It would be expected absent evidence to the contrary that the use of hydrocyclones in a method of isolating and separating encysted protozoa (oocysts from *Eimeria*) would be effective at reducing the potential for error and more closely simulated the separation processes used in industrial operations.

Applicant's Arguments

As amended, the currently claimed invention recites methods for isolating a viable oocyst using a hydrocyclone. Applicant urges that nowhere in the prior art has it been disclosed, taught, or suggested that a hydrocyclone could be used to separate a viable oocyst. Applicant urges that the art teaches away from using a hydrocyclone for use with living organisms as it was previously expected to fatally damage the oocysts due to the intense shear forces. The pending claims 2-6, 8-10 and 23-26 are not rendered obvious by Conkle et al in view of Singh et al.

Applicant urges to establish a case of *prima facie* obviousness, (a) the art must teach or suggest all claim limitations, (b) there must be suggestion or motivation in the art to modify the reference and (c) there must be a reasonable expectation of success. Applicant urges that no case of *prima facie* obviousness has been established.

Applicant urges that neither Conkle et al nor Singh et al either alone or in combination, disclose, teach or suggest using a hydrocyclone to separate viable

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oocysts. Applicant urges that Singh et al use a hydrocyclone to separate starch particles from protein particles in a solution of wet-milled corn. Applicant urges that nowhere do Singh et al disclose or suggest that a hydrocyclone could be successfully used to separate and/or isolate viable oocysts from liquid suspensions. Applicant urges that Singh et al do not cure the failings of Conkle et al as Singh et al fail to provide hydrocyclones with viable oocysts or intact living organisms. Applicant urges that the fact that the wet milling methods of Singh et al inherently destroys cells to isolate starch and protein fragments further teach away from the element of separating a viable oocyst.

Applicant urges that at the time of filing, there was no reason or motivation for combining Conkle et al with Singh et al. Applicant urges that one skilled in the art would have known that use of a hydrocyclone involves extreme sheer forces and that an oocyst may be fatally damaged from agitation, stirring or shaking. Applicant urges that at the time of filing the state of the art taught away from using a hydrocyclone to separate viable oocysts.

Applicant urges that the Office Action asserts that it would have been obvious to use a hydrocyclone because Singh et al taught that using hydrocyclone 'increase the yield of the product, reduced the time required for separation and eliminated the requirement of large floor area. Applicant urges that this reasoning is incorrect. Applicant urges that the yield of cell fragments (i.e.starch and protein) is not pertinent to the separation of viable oocysts. Applicant urges that Singh et al provide no

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disclosures, teachings or suggestions for separating a viable oocyst or any other living organism.

Applicant urges that no case of prima facie obviousness has been established. Applicant urges that a prima facie case of obviousness may be rebutted by showing that the prior art in any material way, teaches away from the claimed invention. Applicant urges that "when the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious" KSR International Co. v. Teleflex Inc., 850 U.S. __, __, 82 USPQ2d 1385, 1395(2007). Applicant urges even if Conkle et al and Singh et al were combined as proposed by the Office, Applicant's assert that there would be no reasonable expectation of success as required by 103.

Applicant urges that Singh et al is non-analogous art that has been mistakenly cited by the Office. Applicant urges that the Singh et al reference is not in the field of Applicant's endeavor nor reasonably pertinent to the particular problem the present Applicants' solved. Applicant urges that Singh et al presupposes the cell is ruptured into small fragments and is nonviable.

Applicant refers to U.S. Patent No.5,547,868 and assert that using hydrocyclone fails to disclose, teach or suggest the separation of any viable oocysts using a hydrocyclone.

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Examiner's Response to Applicant's Arguments

Applicant's arguments filed March 27, 2009 have been fully considered but they are not persuasive.

In response to applicant's argument that no case of *prima facie* obviousness has been established, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Conkle et al teach a method of separating and isolating oocysts from the genus *Eimeria*. Conkle et al do not teach the use of hydrocyclones but suggest the use of other methods of processing oocysts to eliminate the use of harsh chemicals such as potassium dichromate. Singh et al teach a method of using hydrocyclones in separation processes and disclosed the use of the Doxie Type A single hydrocyclone. One of ordinary skill would be motivated to use hydrocyclones over convention methods of separating and isolating oocysts because Singh et al teach using hydrocyclones in separation processes increases the yield of product, reduces the amount of time of the separation process and does not require chemicals such as potassium dichromate. Thus, a case *prima facie* obviousness has been established.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of

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ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to separate and isolate oocysts. It is well known in the art that separation and isolation processes often use hazardous chemicals such as potassium dichromate in these processes. The prior art recognizes that there is a need to improve these processes by eliminating the use of such chemicals. See Conkle et al. The prior art recognizes that the use of hydrocyclones is a method to separate materials. See Singh et al. Thus, it would be obvious to apply a known technique to a known product to be used in a known method that is ready for improvement to yield predictable results. Thus, the combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to contrary.

To address Applicant's comment's regarding Conkle et al and Singh et al, it should be noted that Conkle et al and Singh et al need not individually teach the claimed invention. It should be noted that it is the combination of prior art references that would allow the artisan of ordinary skill to arrive at the claimed invention. As stated above, Conkle et al teach a method of separating and isolating oocysts from the genus *Eimeria*. Conkle et al makes a suggestion that other processes of separating and isolating should be used to eliminate the use of hazardous chemicals such as potassium dichromate. Singh et al teach the use of hydrocyclones in separation

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processes. Therefore, it is known in the art that hydrocyclones are used to separate materials. Thus, One of ordinary skill in the art would have been motivated to use hydrocyclones in a method of separating and isolating oocysts because hydrocyclones increase the yield of the product, reduces processing time (see Singh et al) and does not require chemicals such as potassium dichromate. Therefore, the combination of references teach the claimed invention.

To address Applicant's comments regarding the prior art teaching away from using hydrocyclones to separate live cells, it should be noted that U.S. Patent No. 5,547,858 does not teach away from using hydrocyclones to separate and isolate live cells. In fact, the Patent embraces the use on hydrocyclones to separate and isolate materials from bacterial cells.

U.S. Patent 5,547,858 discloses that " As a result of extensive investigations to solve the foregoing problems, the present inventors have found that by applying a liquid cyclone to a solution containing both crystals and cells, *the crystals can be efficiently concentrated and isolated by the ability of classification of the liquid cyclone and at the same time, the cells having a diameter smaller than that of the crystals, which are considered difficult to apply the liquid cyclone thereto, can be efficiently selected from a concentrated solution of the crystals.*

Accordingly, one object of the invention is to provide a method for purification of an amino acid, a nucleic acid or a derivative thereof comprising treating a crystal slurry containing not greater than 10 wt % of cells having a diameter of not greater than 5 .mu.m on a dry weight basis, and 5 to 60 wt % of crystals of an amino acid, a nucleic acid or derivatives thereof, having a diameter of 10 to 2000 .mu.m, with a liquid cyclone which has a representative diameter capable of sufficiently increasing the concentration of the crystals at the downstream side and, if necessary, applying a back pressure to the downstream side to recover a concentrated solution of crystals having 30 to 90 wt % at the downstream side and select not less than 50% of the cells at the upstream side".

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U.S. Patent No. 5,547,858 teaches that cells can be separated from the solution of crystals. Thus, hydrocyclones can be used to separate and isolate bacterial cells. It should be noted that the claims do not recite that the oocysts are live.

In response to applicant's argument that Singh et al is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, as stated above, Conkle et al teach a method of separating and isolating oocysts. Conkle et al do not teach the use of a hydrocyclone. However, Singh et al teach a method of using hydrocyclones in separation processes and discloses the use of the Doxie Type A single hydrocyclone. One of ordinary skill would be motivated to use hydrocyclones over convention methods of separating and isolating oocysts because Singh et al teach using hydrocyclones in separation processes increases the yield of product, reduces the amount of time of the separation process and does not require chemicals such as potassium dichromate.

In view of all of the above, this rejection is maintained.

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4. The rejection of claims 11-13 under 35 U.S.C. 103(a), is maintained for the reasons set forth on pages 10-12, paragraph 5 of the Final Office Action.

The rejection is reiterated below:

Claims 11-13 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al and Singh et al as applied to claims 2-6, 8-10, and 23-26 and further in view of Sjoerdsma et al (*U.S. Patent No. 4,399, 151 published August 16, 1983*).

The teachings of Conkle et al and Singh et al have been described previously. Conkle et al and Singh et al et al do not teach the use of screens.

Sjoerdsma et al teach that mesh screens can be used to extract debris from biological material (Example 6, column 24).

It would have been *prima facie* obvious at the time the invention was made to include a mesh screen in the method of Conkle et al and Singh et al as combined above because Sjoerdsma et al demonstrate that mesh screens are effective at separating debris or contaminants from biological material. It would be expected that using mesh screens would be an effective way to eliminate contamination from oocysts.

Applicant's Arguments

Applicant urges that the defect of the Office's obviousness rejection is not cured by Sjoerdsma et al. Applicant urges that this reference does not teach or disclose the use of hydrocyclones to separate or isolate oocysts. Applicant urges that the reference discloses that mesh screens can be used to extract debris from biological matters.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed March 27, 2009 have been fully considered but they are not persuasive.

As stated above, Conkle et al teach a method of separating and isolating oocysts from the genus *Eimeria*. Conkle et al makes a suggestion that other processes of separating and isolating should be used to eliminate the use of harsh chemicals such as potassium dichromate. One of ordinary skill in the art would have been motivated to

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use hydrocyclones in a method of separating and isolating oocysts because hydrocyclones increase the yield of the product, reduces processing time and does not require chemicals such as potassium dichromate. Conkle et al nor Singh et al teach the use of mesh screens. However, Sjoerdsma et al teach that mesh screens can be used to extract debris from biological material (Example 6, column 24). One of ordinary skill in the art would be motivated to include a mesh screen in the method of Conkle et al and Singh et al as combined above because demonstrate that mesh screens are effective at separating debris or contaminants from biological material.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to separate and isolate oocysts. It is well known in the art that separation and isolation processes often use hazardous chemicals such as potassium dichromate in these processes. The prior art recognizes that there is a need to improve these processes by eliminating the use of such chemicals. See Conkle et al. The prior art recognizes that the use of hydrocyclones is a method to separate materials. See Singh et al. It well known in the art to separate biological matter using mesh screens. See Sjoerdsma et al. Thus, it would be obvious to apply a known technique to a known product to be used in a known

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method that is ready for improvement to yield predictable results. Thus, the combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to contrary.

5. The rejection of claim 102 under 35 U.S.C. 103(a), is maintained for the reasons set forth on pages 12-14, paragraph 6 of the Final Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 102 is rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al (WO 00/50072 published August 31, 2000) in view of Singh et al (*Cereal Chemistry*, 72(4):344-348, 1995) as applied to claims 2-6, 8-10 and 23-26 above and further in view of Kimura et al (*Journal of Protozoology Research*, July 2000, Vol. 10, No.3, pp. 155-165) (Abstract only).

Claim 102 is drawn to the method of claim 6 wherein the dense aqueous liquid is selected from the group consisting of sucrose and fructose corn syrup.

The teachings of Conkle et al and Singh et al have been described previously.

Conkle et al and Singh et al do not teach the claim limitation "the method of claim 6 wherein the dense aqueous liquid is selected from the group consisting of sucrose and fructose corn syrup".

Kimura et al teach a flotation technique using sucrose (see the Abstract). Kimura et al teach that the sucrose flotation technique is a fast one-step, simple and inexpensive method that allows from the separation and recovery of oocysts (see the Abstract).

It would be *prima facie* obvious at the time the invention was made to modify the separation and isolation procedures as taught by Conkle et al to use the hydrocyclones as taught by Singh et al and the sucrose flotation technique as taught by Kimura et al because Singh et al teach using hydrocyclones in separation processes increases the yield of product, reduces the amount of time of the separation process and does not

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require chemicals such as potassium dichromate and Kimura et al teach that the sucrose flotation technique is a fast one-step, simple and inexpensive method that allows from the separation and recovery of oocysts. It would be expected, absent evidence to the contrary, that the use of hydrocyclones and sucrose flotation in a method of separating and isolating oocysts would be a fast, effective way to isolate and separate encysted protozoa (oocysts from *Eimeria*) without the use of hazardous chemicals.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to separate and isolate oocysts. It is well known in the art that separation and isolation processes often use hazardous chemicals such as potassium dichromate in these processes. The prior art recognizes that there is a need to improve these processes by eliminating the use of such chemicals. See Conkle et al. The prior art recognizes that the use of hydrocyclones is a method to separate materials. See Singh et al. It well known in the art to separate biological matter using mesh screens. See Sjoerdsma et al. It is known in the are to use sucrose flotation to separate and isolate oocysts. See Kimura et al. Thus, it would be obvious to apply a known technique to a known product to be used in a known method that is ready for improvement to yield predictable results. Thus, the combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to contrary.

Applicant's Arguments

Applicant urges that the defect of the Office's obviousness rejection is not cured by Kimura et al. Applicant urges that this reference does not teach or disclose the use of hydrocyclones to separate or isolate oocysts. Applicant urges that even in the flotation technique of Kimura the recovery rate from high turbidity water was significantly lower which may be considered a teaching away from the invention.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed March 27, 2009 have been fully considered but they are not persuasive.

As stated above, Conkle et al teach a method of separating and isolating oocysts from the genus *Eimeria*. Conkle et al makes a suggestion that other processes of separating and isolating should be used to eliminate the use of harsh chemicals such as potassium dichromate. One of ordinary skill in the art would have been motivated to use hydrocyclones in a method of separating and isolating oocysts because hydrocyclones increase the yield of the product, reduces processing time and does not require chemicals such as potassium dichromate. Conkle et al nor Singh et al teach the use of mesh screens. Sjoerdsma et al teach that mesh screens can be used to extract debris from biological material (Example 6, column 24). One of ordinary skill in the art would be motivated to include a mesh screen in the method of Conkle et al and Singh et al as combined above because demonstrate that mesh screens are effective at separating debris or contaminants from biological material. Conkle et al nor Singh et al nor Sjoerdsma et al teach the method of claim 6 wherein the dense aqueous liquid is selected from the group consisting of sucrose and fructose corn syrup". Kimura et al teach a flotation technique using sucrose (see the Abstract). One of ordinary skill in the art would be motivated to added the use of sucrose to the combine method of Conkle et al, Singh et and Sjoerdsma et al as set forth above because Kimura et al teach that the sucrose flotation technique is a fast one-step, simple and inexpensive method that allows from the separation and recovery of oocysts.

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Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results".

Too address Applicant's comment regarding recovery rate from high turbidity water, Kimura et al teach that this technique is a useful, one step, inexpensive method for the separation of oocysts. Kimura et al do not teach away from the claimed invention.

In view of all of the above, this rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-6, 8-10 and 23-26 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al (*WO 00/50072 published August 31, 2000*) in view of Alesina et al (*SU 1637882 A published March 30, 1991, Abstract only*).

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Conkle et al teach methods of isolating and separating oocysts from *Eimeria* species (oocysts known to cause coccidiosis) (see the Abstract). Conkle et al teach that the methods of the invention are used to produce vaccines against avian coccidiosis (see the Abstract). Thus, Conkle et al teach the claim limitation that the host animals are from the class Aves. Conkle et al teach that encysted protozoa (oocysts) are obtained from feces, the suspensions or slurries can include significant amounts of undesirable suspended solids (pages 4-5). Conkle et al teach that the encysted protozoa require centrifugation and concentration of the protozoa (page 6). Conkle et al teach that the suspensions can include from about 1 up to about 20 weight percent solid or feces (page 5). Conkle et al teach that the separation methods of the invention include dense salt solutions including water and sodium chloride (page 5). Conkle et al teach that encysted protozoa need to be separated from suspension to achieved at least 70% encysted protozoa recovery (page 5). Conkle et al teach that encysted protozoa can be recovered or separated by salt flotation or gas flotation (page 5). Conkle et al teach that using salt flotation results in about 80 to 95 percent recovery (page 5). Conkle et al teach that the use of gas flotation results in about 20 to 90 percent recovery of encysted protozoa (page 7). However, Conkle et al teach that that gas flotation process rejects about 20 to 90 percent of encysted protozoa (page 7). Conkle et al teach that a need exists for a more efficient vaccination method (page 2). Conkle et al teach that this need would use other techniques to eliminate hazardous chemical such as potassium dichromate in processing the protozoa included in compositions used to vaccinate animals (page 2).

Conkle et al do not teach the use of hydrocyclones.

Alesina et al that hydrocyclones can be used for microorganism suspension separation (see the Abstract).

It would be *prima facie* obvious at the time the invention was made to modify the separation and isolation procedures as taught by Conkle et al to use hydrocyclones because Alesina et al that hydrocyclones can be used for microorganism suspension separation, It would be expected, absent evidence to the contrary, that the used on hydrocyclones in a method of isolating and separating encysted protozoa (oocysts from *Eimeria*) would be effective at separating microorganism.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to separate and isolate oocysts. It is well known in the art that separation and isolation processes often use hazardous chemicals such as potassium dichromate in these processes. The prior art recognizes that there is a need to improve these processes by eliminating the use of such chemicals. See Conkle et al. Thus, the art recognizes that hazardous chemicals often are a problem in separation techniques known in the art. The prior art recognizes that the use of hydrocyclones is a method to separate materials. See

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Alesina et al. Thus, it would be obvious to apply a known technique to a known product to be used in a known method that is ready for improvement to yield predictable results. Thus, the combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to contrary.

7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al and Alesina et al as applied to claims 2-6, 8-10 and 23-26 and further in view of Sjoerdsma et al (*U.S. Patent No. 4,399, 151 published August 16, 1983*).

The teachings of Conkle et al and Alesina et al have been described previously. Conkle et al and Singh et al et al do not teach the use of screens.

Sjoerdsma et al teach that mesh screens can be used to extract debris from biological material (Example 6, column 24).

It would have been *prima facie* obvious at the time the invention was made to include a mesh screen in the method of Conkle et al and Alesina et al as combined above because demonstrate that mesh screens are effective at separating debris or contaminants from biological material. It would be expected, absent evidence to the contrary that using mesh screens would be an effective way to eliminate contamination from oocysts.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR*

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International Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007) also discloses that “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results”. Thus, the combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to contrary.

8. Claim 102 is rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al, Alesina et al and Sjoerdsma et al as applied to claims 2-6, 8-13 and 23-26 above and further in view of Kimura et al (*Journal of Protozoology Research*, July 2000, Vol. 10, No.3, pp. 155-165) (Abstract only).

Claim 102 is drawn to the method of claim 6 wherein the dense aqueous liquid is selected from the group consisting of sucrose and fructose corn syrup.

The teachings of Conkle et al and Alesina et al have been described previously.

Conkle et al and Alesina et al do not teach the claim limitation “the method of claim 6 wherein the dense aqueous liquid is selected from the group consisting of sucrose and fructose corn syrup”.

Kimura et al teach a flotation technique using sucrose (see the Abstract). Kimura et al teach that the sucrose flotation technique is a fast one-step, simple and inexpensive method that allows from the separation and recovery of oocysts (see the Abstract).

It would be *prima facie* obvious at the time the invention was made to modify the separation and isolation procedures as taught by Conkle et al to use the hydrocyclones

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as taught by Alesina et al and the sucrose flotation technique as taught by Kimura et al because Alesina et al teach using hydrocyclones are used to separate microorganisms and Kimura et al teach that the sucrose flotation technique is a fast one-step, simple and inexpensive method that allows from the separation and recovery of oocysts. It would be expected, absent evidence to the contrary, that the use of hydrocyclones and sucrose flotation in a method of separating and isolating oocysts would be a fast, effective way to isolate and separate encysted protozoa (oocysts from *Eimeria*) without the use of hazardous chemicals.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to separate and isolate oocysts. It is well known in the art that separation and isolation processes often use hazardous chemicals such as potassium dichromate in these processes. The prior art recognizes that there is a need to improve these processes by eliminating the use of such chemicals. See Conkle et al. The prior art recognizes that the use of hydrocyclones is a method to separate microorganisms. See Alesina et al. It is known in the are to use sucrose flotation to separate and isolate oocysts. See Kimura et al. Thus, it would be obvious to apply a known technique to a known product to be used in

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a known method that is ready for improvement to yield predictable results. Thus, the combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to contrary.

Status of Claims

9. No claims are allowed.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Examiner, Art Unit 1645
June 19, 2009